

**EWG M2 Recommendation to the ICH Steering Committee**  
**Electronic Standards for the Transfer of Regulatory Information (ESTRI)**  
**Format - Recommendation 5.3    16JUL1997**

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**Title: EDI Header Specification for the E2B Message**

**Date: July 16, 1997**

**Background:**

To establish an ICH standard for implementation of EDI, it is important to define the EDI interchange header and E2B message header to facilitate the management and tracking of EDI transmissions. For secure EDI over the Internet, see Recommendation 4.1.

The objective of EDI is to establish an automated database to database interchange of data records. The EDI interchange header will enable automated electronic transmission. However, it contains no instructions or explanation of the contents. Therefore, an E2B message header has been defined to allow automated processing of expedited E2B individual case safety reports.

**Recommendation:**

**EDI Interchange Header**

The M2 Expert Working Group recommends the use of the international standard (ISO 9735) UN/EDIFACT interchange header (UNB) and the UN/EDIFACT interchange trailer (UNZ). The combination of the header and trailer form an "EDI Envelope" which supports local routing. The fields of this header will define details such as the format of the transmission, the identification of the sender and receiver, a unique transmission ID, and date/time.

**E2B Message Header**

This file defines a content-specific envelope (inside of the EDI envelope) which provides data processing information to the application. In order to maintain a syntax consistent with the E2B message (Recommendation 5.2), the header is defined in an SGML DTD. It is comprised of a general description of content, format and version of message.

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Field Name	SGML DTD Descriptor	Description	Length/Type	Values
Message type	messagetype	Type of information being transmitted	6AN	E2B (Individual case safety report)
Message Format Version	messageformatversion	Version number of Message Format	3AN	
Message Format Release	messageformatrelease	Release number of the Message Format	3AN	

**Remarks:**

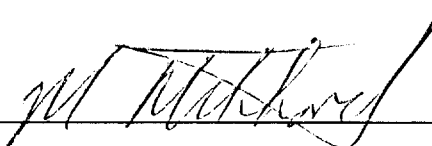
**SIGNATURES**

**Topic Leader:**


<EU>



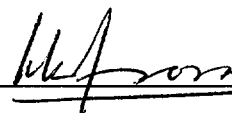
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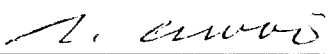
<PhRMA>



<MHW>



<JPMA>



**Observer:**

<HPB>

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